IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	Ream, et al.
Appl. No.:	09/990,628
Conf. No.:	4209
Filed:	November 13, 2001
Title:	OVER-COATED CHEWING GUM FORMULATIONS
Art Unit:	1615
Examiner:	S. Howard
Docket No.:	112703-203

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-COMPLIANT APPEAL BRIEF

Sir:

This Response is submitted in reply to the Notice of Non-Compliant Appeal Brief dated February 5, 2008.

REMARKS

In response to the Notice of Non-Compliant Appeal Brief dated February 5, 2008, Appellants have amended the Status of Claims section of the Appeal Brief to address the informalities cited by the Patent Office. The compliant version of the Appeal Brief is attached as Exhibit A without copies of the cited references, affidavits, office actions, advisory actions and responses to office actions, which were previously submitted.

Appellants submit that the present Appeal Brief is compliant under 37 CFR 41.37. Appellants respectfully request reconsideration of the Appeal Brief and submit that the Patent Office has failed to establish a *prima facie* case of obviousness with respect to the rejection of the claimed invention. Accordingly, Appellants respectfully submit that the obviousness rejection is erroneous in law and in fact and should therefore be reversed.

The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-203 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No. 29156

Dated: March 3, 2008

Exhibit A

THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s):	Ream, et al.
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APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on November 19, 2007. This Appeal is taken from the Final Rejection dated August 22, 2007.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on appeal is Wm. Wrigley Jr. Company by virtue of an Assignment dated October 11, 2001, October 17, 2001 and October 30, 2001 and recorded at the United States Patent and Trademark Office at reel 012321, frame 0775.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and the Assignee of the above-identified patent application note that there are no related appeals or interferences in this application.

III. STATUS OF CLAIMS

Claims 9-26 are pending in the above-identified patent application. Claims 1-8 and 27-34 were previously withdrawn. No Claims have been allowed previously. Claims 9-26 stand rejected. Claims 9-26 are being appealed in this Brief. A copy of the appealed claims is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Final Office Action was mailed on August 22, 2007. Appellants filed a Response to the Final Office Action on October 9, 2007. An Advisory Action was mailed on October 31, 2007. In the Advisory Action, the Response was considered but was deemed not to place the patent application in condition for allowance. A copy of the Final Office Action is attached as Exhibit A in the Evidence Appendix and a copy of the Advisory Action is attached as Exhibit B in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification (a copy of which is attached as Exhibit C in the Evidence Appendix) for each of the independent claims (Claims 9 and 18) is provided as follows:

Independent Claim 9 is directed to a chewing gum (page 4, lines 10-20) comprising a gum center (page 4, lines 23-25 and page 15, line 5 to page 18, line 10); and a coating comprising a medicament that surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum product, the medicament being designed to be delivered into the systemic system of a patient (page 1, lines 11-13; page 4, lines 25-27; page 5, lines 23-31, and page 9, lines 5-20).

Independent Claim 18 is directed to a product including a medicament that is designed to function by being delivered through the systemic system of an individual (page 1, lines 11-13; page 4, lines 9-10, and page 12, lines 5-16) comprising a chewing gum center (page 4, lines 23-25 and page 15, line 5 to page 18, line 10); and a coating that at least substantially surrounds the chewing gum center and comprises a medicament and a high-intensity sweetener, the coating comprising at least 50% by weight of the product (page 1, lines 11-13; page 4, lines 25-27; page 5, lines 23-31, and page 9, lines 5-20).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 9-26 stand rejected under 35 U.S.C. §103(a) as being obvious over the combination of U.S. Patent No. 4,317,838 to Cherukuri et al. ("*Cherukuri*") in view of WO 99/44436 to Stahl et al. ("*Stahl*"). A copy of *Cherukuri* is attached as Exhibit D in the Evidence Appendix. A copy of *Stahl* is attached as Exhibit E in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS - Obviousness under 35 U.S.C. §103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made…The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art…Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness…Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Moreover, the Patent Office must provide explicit reasons why the claimed invention is obvious in view of the prior art. The Supreme Court emphasized that when formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR v. Teleflex*, 550 U.S. __ (2007), 127 S.Ct. 1727.

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the

path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE CLAIMED INVENTION

Independent Claim 9 is directed to a chewing gum comprising a gum center and a coating that surrounds the gum center. The coating comprises a medicament that is designed to be delivered into the systemic system of a patient. The coating comprises at least 50% by weight of the chewing gum.

Independent Claim 18 is directed to a product including a medicament. The product is designed to function by being delivered through the systemic system of an individual. The product comprises a chewing gum center and a coating that at least substantially surrounds the chewing gum center, comprising at least 50% by weight of the product. The coating comprises a medicament and a high-intensity sweetener.

Appellants have found that chewing a coated chewing gum with a medicament or agent in the coating, or in certain situations even placing the coated chewing gum in the mouth, releases the medicament or agent from the chewing gum. Continuing to chew the chewing gum creates a pressure within the buccal cavity forcing the agent or medicament directly into the systemic system of the individual through the oral mucosa contained in the buccal cavity. This greatly enhances the absorption of the medicament or agent into the systemic system of the individual as well as the bioavailability of the medicament or agent within the system.

Appellants have also found that an increase in the absorption of the medicament or agent through the oral mucosa is achieved when compared to typical oral administration. In other words, the medicament or agent is absorbed into the system of an individual more quickly through the oral mucosa than if it was swallowed as in a typical oral administration. Indeed, the absorption of the medicament or agent through the oral mucosa approaches that of a parental administration (e.g. intravenous or intramuscular injection), and bioavailability is also much greater than oral administration. Teachings and examples in the specification supporting and elucidating the scope of the present invention include page 1, lines 11-13; page 4, lines 9-20 and 23-25; page 5, lines 23-31; page 9, lines 5-20; page 12, lines 5-16, and page 15, line 5 to page 18, line 10.

C. THE REJECTION OF CLAIMS 9-26 SHOULD BE REVERSED BECAUSE THE PATENT OFFICE HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

The Examiner asserts that the combination of *Cherukuri* and *Stahl* renders obvious Claims 9-26. Independent Claims 9 and 18 recite, in part, a product comprising a gum center and a coating comprising at least 50% by weight of the chewing gum product. In contrast, Appellants respectfully submit that *Cherukuri* and *Stahl* are deficient with respect to elements of Claims 9-26 as detailed below.

Cherukuri is directed to a so-called "one step" or "one syrup" method for providing a sugarless coating on a solid center, which includes applying alternating layers of coating syrup and dusting mix. See, *Cherukuri*, column 2, lines 14-30. As a result, rather than teaching overall coating levels, *Cherukuri* emphasizes the components of the coating syrup and dusting mix as well as specific ingredient percentages within the coating syrup and dusting mix. See, *Cherukuri*, column 2, lines 40-55 and column 3, line 51 to column 4, line 4. If fact, none of the weight percentages disclosed teach a coating comprising at least 50% by weight of the overall product. Instead, the highest, and only, coating level disclosed in *Cherukuri* is 35 weight percent of the coated chewing gum tablet. See, *Cherukuri*, column 4, lines 29-34 and column 7, lines 13-19. Therefore, as admitted in the Office Action dated August 22, 2007 (refer to Exhibit A), *Cherukuri* fails to disclose or suggest a coating comprising at least 50% by weight of the chewing gum product as required, in part, by Claims 9 and 18.

However, in the Advisory Action dated October 31, 2007 (refer to Exhibit B), the Examiner asserts that column 4, lines 29-34 of *Cherukuri* teaches one skilled in the art how to obtain at least 50% by weight coating since *Cherukuri* clearly teaches that 10-12 coats of coating syrup and 7-9 coats of dusting mix are required for 35% by weight of chewing gum. Based on these numbers, the Examiner asserts that one skilled in the art, by routine experimentation, could calculate the number of sugar coatings and dusting mixes required to achieve the at least 50% by weight coating of the present claims, and then apply that number of syrup and dusting coats. Appellants respectfully disagree and respectfully submit that one having skill in the art would have no reason, in view of *Cherukuri*, to increase the coating level from a typical level of 35% to the presently claimed coating level of at least 50%.

The present claims provide improved products for delivering a medicament or agent to an individual. To this end, chewing gum, specifically a coated chewing gum product, is provided including a medicament or agent. The medicament or agent is present within the coating. The coating substantially encloses a gum center (the water soluble portion and insoluble base portion) and comprises at least 50% by weight of the product. In other words, the coating comprising the medicament must have a weight equal to or greater than that of the gum center.

By having a coating comprising at least 50% by weight of the entire chewing gum product, a larger amount of medicament or agent can be placed in the coating. As a result, chewing the gum releases more medicament or agent into the saliva in higher concentrations. See, specification, page 12, lines 22-24. A higher concentration of medicament or agent in the saliva results in a higher concentration gradient in the oral cavity. This improves absorption of the medicament or agent through the oral mucosa. See, specification, page 9, lines 5-20.

Moreover, in contrast to typical coated chewing gum products, the products of the present invention include an increased coating level of at least 50% by weight coating. See, specification, page 13, lines 27-28. This increased coating level also allows certain medicaments to achieve high enough levels to perform an intended medicinal purpose. Further, this high coating level allows the coating to function as a masking agent. See, specification, page 14, lines 1-8.

In contrast to the above, one skilled in art would have no reason, in view of *Cherukuri*, to increase the coating level from the typical level of 35% to the "over-coated" level of at least 50%. As stated above, the claims require a coated chewing gum where the coating comprising the medicament must have a weight equal to or greater than that of the gum center. It would clearly be out of the norm to have a coated chewing gum with more coating than actual chewing gum. As a result, it is essential to establish a reason to achieve such a high level of coating.

As stated previously, *Cherukuri* is directed to a so-called "one step" or "one syrup" method for providing a sugarless coating on a solid center which includes applying alternating layers of coating syrup and dusting mix. When that solid center is a coated chewing gum, *Cherukuri* states that 10-12 coats of coating syrup and 7-9 coats of dusting mix may be required, as asserted by the Examiner above, to achieve a 35% by weight coating. *Cherukuri* also teaches that the number of applications will also vary depending on the amount of solids present in the

coating syrup, the amount of dusting mix employed, and the type of comestible to be coated. See, *Cherukuri*, column 4, lines 35-39.

However, *Cherukuri* already teaches a specific coating procedure and coating level (35%) for coated chewing gum. Moreover, *Cherukuri* fails to teach that the weight percentage of coating can vary from this established level for coated chewing gum. Instead, *Cherukuri* teaches that the number of applications can vary based on factors such as amount of solids in the coating syrup. Using the above teachings in *Cherukuri*, if the solids level in a coating syrup is low, the number of coating syrup applications can increase to meet the 35 weight % established form coating in a coated chewing gum. However, this still does not teach or provide any reason for increasing the overall coating weight percentage above the 35% that *Cherukuri* establishes for a coated chewing gum. Moreover, *Cherukuri* does not teach medicament or agent use in the coating as a reason for varying the number of coating syrup/dusting mix applications. Therefore, *Cherukuri* provides no reason why one skilled in the art would increase the weight percentage of coating in a chewing gum from 35% to at least 50%.

Accordingly, though the Examiner asserts that routine experimentation would lead one skilled in the art to achieve the at least 50% by weight coating in view of the teaching in *Cherukuri*, the Examiner clearly does not establish a reason why one skilled in the art would want to achieve the at least 50% by weight coating of the present claims.

Stahl also fails to disclose or suggest a coating comprising at least 50% by weight of the product as required, in part, by independent Claims 9 and 18. Instead, the Examiner relies upon *Stahl* for arguably teaching a medicament in the coating along with a sweetener, an element the Office Action admits *Cherukuri* lacks.

Appellants have found that chewing a coated chewing gum with a medicament or agent in the coating, or in certain situations even placing the coated chewing gum in the mouth, releases the medicament or agent from the chewing gum. Continuing to chew the chewing gum creates a pressure within the buccal cavity forcing the agent or medicament directly into the systemic system of the individual through the oral mucosa contained in the buccal cavity. This greatly enhances the absorption of the medicament or agent into the systemic system of the individual as well as the bioavailability of the medicament or agent within the system. See, specification, page 9, lines 5-20 (Exhibit C).

Appellants have also found that an increase in the absorption of the medicament or agent through the oral mucosa is achieved when compared to typical oral administration. In other words, the medicament or agent is absorbed into the system of an individual more quickly through the oral mucosa than if it was swallowed as in a typical oral administration. Indeed, the absorption of the medicament or agent through the oral mucosa approaches that of a parental administration (e.g. intravenous or intramuscular injection), and bioavailability is also much greater than oral administration. See, specification, page 9, lines 5-20 and page 11, lines 29-31 (Exhibit C).

In sum, *Cherukuri* and *Stahl* fail to disclose or suggest every element of the present claims and fail to even recognize the advantages, benefits and/or properties of a consumable product having coating comprising at least 50% by weight of the product in accordance with the present claims.

For at least the reasons discussed above, the combination of *Cherukuri* and *Stahl* fails to teach, suggest, or even disclose all of the elements of Claims 9 and 18 and Claims 10-17 and 19-26 that depend from Claims 9 and 18, and thus, fail to render the claimed subject matter obvious.

VIII. CONCLUSION

Appellants further submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) with respect to the rejection of Claims 9-26. Accordingly, Appellants respectfully submit that the obviousness rejection is erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-203 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY _____

Robert M. Barrett
Reg. No. 30,142
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Dated: March 3, 2008

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 09/990,628

9. A chewing gum comprising:

a gum center; and

a coating comprising a medicament that surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum product, the medicament being designed to be delivered into the systemic system of a patient.

10. The chewing gum of Claim 9 wherein the medicament is selected from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; stimulants; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; and cardiovascular agents.

11. The chewing gum of Claim 9 wherein the coating includes a sufficient amount of taste masking agent to provide acceptable organoleptic properties.

12. The chewing gum of Claim 11 wherein the taste masking agent is selected from the group consisting of: zinc gluconate, ethyl maltol, glycine, acesulfame-k, aspartame; saccharin; fructose; xylitol; isomalt; maltitol; spray dried licorice root; glycerrhizine; sodium gluconate; glucono delta-lactone; ethyl vanillin; dextrose; sucralose; vanillin; and ethyl maltol.

13. The chewing gum of Claim 11 wherein the taste masking agent comprises approximately 30% to about 99% by weight of the coating.

14. The chewing gum of Claim 9 wherein the coating includes approximately 0.5% to about 5% by weight of a high-intensity sweetener chosen from the group consisting of aspartame, sucralose, saccharine, and acesulfame-k.

15. The chewing gum of Claim 9 wherein the gum center includes at least 50% by weight water-insoluble gum base.

16. The chewing gum of Claim 9 wherein the coating does not have a shellac layer.

17. The chewing gum of Claim 9 wherein the gum center and coating are sugar-free.

18. A product including a medicament that is designed to function by being delivered through the systemic system of an individual comprising:

a chewing gum center; and

a coating that at least substantially surrounds the chewing gum center and comprises a medicament and a high-intensity sweetener, the coating comprising at least 50% by weight of the product.

19. The product of Claim 18 wherein the medicament is selected from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; stimulants; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; and cardiovascular agents.

20. The product of Claim 18 wherein the coating includes a sufficient amount of taste masking agent to provide acceptable organoleptic properties.

21. The product of Claim 18 wherein the taste masking agent is selected from the group consisting of: zinc gluconate, ethyl maltol, glycine, acesulfame-k, aspartame; saccharin; fructose; xylitol; isomalt; maltitol; spray dried licorice root; glycerrhizine; sodium gluconate; glucono delta-lactone; ethyl vanillin; dextrose; sucralose; vanillin; and ethyl maltol.

22. The product of Claim 18 wherein the taste masking agent comprises approximately 30% to about 99% by weight of the coating.

23. The product of Claim 18 wherein the coating includes approximately 0.5% to about 5% by weight of a high-intensity sweetener chosen from the group consisting of aspartame, sucralose, saccharine, and acesulfame-k.

24. The product of Claim 18 wherein the coating comprises at least 70% by weight powder when it is applied to the gum center.

25. The product of Claim 18 wherein the product is sugar-free.

26. The product of Claim 18 wherein the coating does not have a shellac layer.

EVIDENCE APPENDIX

EXHIBIT A: Final Office Action mailed on August 22, 2007.

EXHIBIT B: Advisory Action mailed on October 31, 2007.

EXHIBIT C: Original Specification

EXHIBIT D: U.S. Patent No. 4,317,838 to Cherukuri et al. ("*Cherukuri*")

EXHIBIT E: WO 99/44436 to Stahl et al. ("*Stahl*")

RELATED PROCEEDINGS APPENDIX

None.